Complete Summary

GUIDELINE TITLE

Prevention and control of meningococcal disease: recommendations for use of meningococcal vaccines in pediatric patients.

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention and control of meningococcal disease: recommendations for use of meningococcal vaccines in pediatric patients. Pediatrics 2005 Aug;116(2):496-505. PubMed

GUIDELINE STATUS

This is the current release of the guideline.

American Academy of Pediatrics (AAP) Policies are reviewed every 3 years by the authoring body, at which time a recommendation is made that the policy be retired, revised, or reaffirmed without change. Until the Board of Directors approves a revision or reaffirmation, or retires a statement, the current policy remains in effect.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

On October 3, 2005, The U.S. Food and Drug Administration (FDA) and CDC notified consumers and health care providers of five reports of Guillain Barre Syndrome following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature. Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization. Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Meningococcal disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Health Plans
Hospitals
Managed Care Organizations
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide the rationale for use of meningococcal conjugate vaccine (MCV4) in adolescents and to update recommendations for use of the meningococcal polysaccharide vaccine (MPSV4) in pediatric patients

TARGET POPULATION

- Pediatric patients aged 11 years and older
- Children 2 to 10 years of age at increased risk of meningococcal disease

INTERVENTIONS AND PRACTICES CONSIDERED

1. Annual visits to a health care professional
2. Immunization with:
    - Tetravalent meningococcal (A,C,Y,W-135) polysaccharide vaccine (MPSV4 [Menomune-A/C/Y/W-135])
    - Tetravalent meningococcal (A,C,Y,W-135) conjugate vaccine (MCV4 [Menactra])
3. Reimmunization of individuals previously vaccinated

MAJOR OUTCOMES CONSIDERED

- Rate of meningococcal disease among vaccinated populations
- Occurrence of outbreaks of meningococcal disease
- Immunogenicity and clinical efficacy of meningococcal vaccines
- Duration of protection after meningococcal vaccination
- Adverse reactions following immunization

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Rating System of Quality of Scientific Evidence

I. Evidence obtained from at least 1 properly designed, randomized, controlled trial

II-1. Evidence obtained from well-designed, controlled trials without randomization

II-2. Evidence obtained from well-designed cohort or case-control analytic studies, preferentially from more than 1 center or group

II-3. Evidence obtained from multiple time series with or without intervention or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost of Meningococcal Vaccines

Whether universal immunization of adolescents with tetravalent A, C, Y, W-135 meningococcal vaccine would result in a net cost or a net savings to society is dependent on invasive meningococcal disease (IMD) incidence, which varies by year, the rates of death or permanent sequelae, and the cost of immunization. A recent study from the U.S. Centers for Disease Control and Prevention (CDC) suggests that universal immunization of adolescents would be cost-effective. However, variations in the epidemiology of and outcomes from IMD by region make it impossible to generate a precise estimate of cost-benefit. If, as expected, universal adolescent immunization with meningococcal conjugate vaccine (MCV4) becomes a reality in the next few years, more precise estimates should become available.

The total cost of immunizing a single adolescent with MCV4 includes direct and indirect costs. The direct costs include supplies (e.g., vaccine [MCV4 = $82.00 and meningococcal polysaccharide vaccine (MPSV4) = $86.10 per dose], syringe with needle), personnel, and administrative expenses. Public and private insurers should be responsible for payment of costs for MCV4. MCV4 is included in the Vaccines for Children program. For private insurers, avoiding financial responsibility by transferring this to intermediate risk-bearing entities (e.g., independent practice associations or other physician groups), individual physicians, or college health services will result in adolescents not being immunized in a timely fashion. Physicians incur significant administrative expenses ensuring that adolescents are immunized with recommended vaccines in a timely fashion, including explaining risk and benefits of immunization to adolescents and parents; ordering, purchasing, storing, and administering the vaccine; recording immunizations in records; and other activities. Physicians should receive reimbursement for expenses associated with each vaccine administration.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grades (I-III) are defined at the end of the "Major Recommendations" field.

1. Two cohorts of adolescents should be immunized routinely with meningococcal conjugate vaccine (MCV4): 1) young adolescents at the 11- to 12-year visit; and 2) adolescents at high school entry or 15 years of age, whichever comes first (both evidence grade I). Within 3 years, the goal will be routine immunization of all adolescents with MCV4 beginning at 11 years of age.
2. Adolescents should visit a health care professional at 11 to 12 years of age, when immunization status and other preventive services can be addressed. Subsequent annual visits throughout adolescence also are recommended for all adolescents.
3. Entering college students who plan to live in dormitories should be immunized with MCV4 routinely (evidence grade II-2).
4. People at increased risk of meningococcal disease should be immunized with MCV4 if they are at least 11 years of age. These persons include:
    - Adolescents who have a terminal complement deficiency or adolescents who have anatomic or functional asplenia (evidence grade II-3)
    - Adolescents who travel to or reside in countries where Neisseria meningitidis is hyperendemic or epidemic (U.S. Centers for Disease

Control and Prevention [CDC] Travelers' Health Hotline 877/FYI-TRIP or online at www.cdc.gov/travel/) (evidence grade II-3)

5. Because people with human immunodeficiency virus (HIV) infection are likely to be at higher risk of meningococcal disease, although not to the extent that they are at risk of invasive Streptococcus pneumoniae infection, they may elect to be immunized with MCV4 if they are at least 11 years of age.
6. Children 2 to 10 years of age at increased risk of meningococcal disease (see recommendations 3 and 4) should be immunized with meningococcal polysaccharide vaccine (MPSV4), because MCV4 is not yet licensed for use in these children.
7. People who wish to decrease their risk of meningococcal disease may elect to receive MCV4 if they are 11 years or older.
8. For control of meningococcal outbreaks caused by vaccine-preventable serogroups (A, C, Y, or W-135), MPSV4 or MCV4 should be used for people 11 years or older (evidence grade II-2). MCV4 is preferred, but MPSV4 is acceptable. For children 2 to 10 years of age, MPSV4 should be used.
9. Immunization with MCV4 may be indicated for adolescents previously immunized with MPSV4. These people should be considered for reimmunization 3 to 5 years after receiving MPSV4 if they remain at increased risk of meningococcal disease.
10. Public and private insurers should be responsible for payment of costs of MCV4, its administration to adolescents for whom MCV4 is recommended, and administrative costs involved in providing vaccines to high-risk people.

Evidence Grading

I. Evidence obtained from at least 1 properly designed, randomized, controlled trial

II-1. Evidence obtained from well-designed, controlled trials without randomization

II-2. Evidence obtained from well-designed cohort or case-control analytic studies, preferentially from more than 1 center or group

II-3. Evidence obtained from multiple time series with or without intervention or dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s)

III. Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is provided for selected recommendations (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Prevention of meningococcal disease and its sequelae

POTENTIAL HARMS

Adverse Reactions Following Immunization

- Among adolescents 11 to 18 years of age, safety of administering tetravalent meningococcal conjugate vaccine (MCV4) and tetravalent meningococcal polysaccharide vaccine (MPSV4) was assessed in 2 randomized controlled trials. The percentage of subjects reporting systemic adverse events was similar in both groups (see Table 4 in the original guideline document). Approximately half of the adolescents experienced at least one systemic adverse reaction, but less than 5% experienced at least one severe systemic reaction. Fever was reported by 3.4 to 5.1% of adolescents who received MCV4 and by 2.5 to 3.0% of adolescents who received MPSV4, a difference that was not significant.
- Local adverse reactions were more common among adolescents who received MCV4 than among adolescents who received MPSV4 (Table 5 of the original guideline document). Of adolescents who received MCV4, 13.1 to 16.9% reported pain that limited movement in the arm of injection, compared with 2.6 to 3.9% of adolescents who received MPSV4. These differences in frequency of local reactions could be attributable in part to different methods of administering the 2 vaccines (MCV4 is administered intramuscularly; MPSV4 is administered subcutaneously). The frequency of local adverse reactions reported after MCV4 administration was similar to that reported after tetanus and diphtheria (Td) administration, which, like MCV4, is given intramuscularly.

CONTRAINDICATIONS

CONTRAINDICATIONS

Immunization with meningococcal conjugate vaccine (MCV4) is contraindicated among people known to have hypersensitivity to any component of the vaccine, including diphtheria toxoid, and to dry, natural rubber latex, which is used in the vial stopper.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Academy of Pediatrics Committee on Infectious Diseases. Prevention and control of meningococcal disease: recommendations for use of meningococcal vaccines in pediatric patients. Pediatrics 2005 Aug;116(2):496-505. PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 May 25

GUIDELINE DEVELOPER(S)

American Academy of Pediatrics - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Pediatrics

GUIDELINE COMMITTEE

Committee on Infectious Diseases

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Academy of Pediatrics (AAP) Policy Web site.

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 25, 2005. The information was verified by the guideline developer on August 23, 2005. This summary was updated by ECRI on October 5, 2005 following the U.S. Food and Drug Administration (FDA) advisory on Menactra (Meningococcal Conjugate Vaccine A, C, Y, and W135).

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